



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
New Orleans District  
Nashville Branch Office  
297 Plus Park Blvd.  
Nashville, TN 37217

Telephone: 615-781-5380  
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November 25, 2003

**VIA FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Gordon L. Hixon, M.D., President  
American Mammographics, Inc.  
1302 Shawhan Terrace  
Chattanooga, Tennessee 37411-2221

Warning Letter No. 2004-NOL-05

Dear Dr. Hixon:

During an inspection of your establishment on October 15-16, 2003, our investigator determined that you are responsible for the manufacturing of mammography accessory devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), which are used in mammography procedures.

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) for medical devices, as specified in Title 21, *Code of Federal Regulations* (CFR), Part 820.

The inspection revealed no device master records [21 CFR 820.181], no procedures for acceptance and rejection of finished devices [21 CFR 820.80(d)], no device history records [21 CFR 820.184], no design control procedures [21 CFR 820.30(a)], failure to evaluate capability of potential suppliers and contractors [21 CFR 820.50(a)], failure to conduct quality audits [21 CFR 820.22] and inadequate complaint procedures [21 CFR 820.198(e)(5)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the cause of the violations identified by the FDA.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

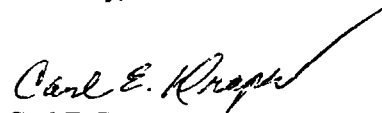
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. There actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step begin taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not occur.

If corrective action cannot be completed within fifteen (15) working days, please state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Carl E. Draper  
District Director  
New Orleans District

Enclosure: 21 CFR Part 820

cc: Adrian J. Palmer  
Director of Sales, Marketing, Applications  
American Mammographics, Inc.  
1302 Shawhan Terrace  
Chattanooga, Tennessee 37411-2221